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C T F A
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

OTC #560-2237

May 25, 2000

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: Topical Antimicrobial Drug Products - Health Care Antiseptic Drug Products for OTC Human Use (Docket No. 75N-183H)

Dear Dr. Ganley:

On September 29, 1999 the Soap and Detergent Association (SDA) and The Cosmetic, Toiletry, and Fragrance Association (CTFA) Industry Coalition submitted an extensive briefing document to FDA. This document provided a consolidated proposal for finished product test methodology for topical antimicrobial products in response to the June 17, 1994 Tentative Final Monograph for Health Care Antiseptic Drug Products. On November 3, 1999 the SDA/CTFA Industry Coalition met with the Agency to discuss the finished product efficacy test method proposal.

During the meeting the Agency gave the Industry Coalition useful direction on a number of specific topics relating to test methodology. At the conclusion of the meeting, Agency personnel indicated that FDA planned to provide a formal Feedback Letter by the end of 1999 summarizing the conclusions and data requests from the meeting, and addressing the method-specific, detail-orientated issues described in the briefing document.

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To date, the Industry Coalition has not received FDA's Feedback Letter. The Industry Coalition believes that establishing standardized, current and flexible finished product test methods is a fundamental first step in progressing with rule-making. Valid and reproducible test methods are needed before clearly defined performance criteria can be established for topical antimicrobial products. Performance criteria must be linked to specific test methods as the outcome of testing will be dependent on both the finished product tested and the specific details of the testing protocol.

The Industry Coalition is committed to working with FDA to finalize the OTC monograph for topical antimicrobial products. The issue of finished product test methodology is so critical to this effort that we urge the Agency to complete their evaluation of the test methodology proposal, before considering other aspects of the rule-making. Consequently, the Industry Coalition respectfully requests that the FDA Feedback letter promised at the November meeting be issued as soon as possible.

Respectfully submitted,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association

Jenan Al-Atrash, Dr. PH
Director, Human Health & Safety
The Soap & Detergent Association

cc: Robert J. DeLap, M.D. (HFD-105)
Linda Katz, M.D. (HFD-560)
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